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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

PHILLIP RACIES, On Behalf of Himself
and All Others Similarly Situated,

Plaintiff,

vs.

QUINCY BIOSCIENCE, LLC, a
Wisconsin limited liability company,

Defendant.

Case No. 3:15-cv-00292 HSG

**DEFENDANT'S OPPOSITION TO
PLAINTIFF'S MOTION FOR
PARTIAL SUMMARY JUDGMENT**

Date: February 4, 2016

Time: 2:00 p.m.

Place: Courtroom 15

Complaint Filed: January 21, 2015

Trial Date: None Set

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I. INTRODUCTION

Plaintiff's instant motion for partial summary judgment resembles a game of three-card monte. Much like the ostensible card game of chance, the motion is initially and seemingly straightforward, yet it becomes altogether mystifying as it unfolds. Once the game plays out, however, the misdirection and sleight of hand are, in hindsight, easily recognizable.

Plaintiff's motion first sets the stage by correctly acknowledging the rules at hand as identified by this Court: that in order to proceed with his lawsuit, Plaintiff must meet his burden of proving the only currently pending issues: whether "the apoeaquorin [(“AQ”)] in the [Defendant's] product [Prevagen®] is destroyed by the human digestive system or is of such a trivial amount that it cannot biologically affect memory or support brain function.” (Doc. No. 34 at 6; Doc. No. 62 at 1:7–14.) The Court identified these issues as Plaintiff's “body chemistry allegations.” (*Id.*) Plaintiff argues he has met his burden of proving his body chemistry allegations in light of three purported opinions of his sole expert: that (1) AQ is no different than any other protein and is “completely” and “fully” digested into amino acids; (2) the amount of AQ in Prevagen® only provides a trivial amount of amino acids; and (3) Prevagen® cannot pass the blood-brain barrier (“BBB”) and can never enter the brain. (Doc. No. 62 at 1:15–2:4.) But, just as the shill plays along in the game of three-card monte to give it an appearance of credibility to unsuspecting participants, Plaintiff's expert similarly proffers irrelevant and untested opinions to create the false perception that Plaintiff's motion is supported by credible scientific evidence.

In reality, Plaintiff's expert proffers zero affirmative evidence that AQ is completely destroyed. In fact, Plaintiff's expert is admittedly no expert on protein digestion at all. He has never studied or tested Prevagen® or AQ, and none of the articles he relied upon for his opinions specifically concern AQ. Perhaps most significantly, Plaintiff's expert further admitted in his report and during his deposition that Prevagen® is *not* “completely” or “fully” digested. Rather, AQ is broken down

1 into *both* single amino acids *and small chains of amino acids, called peptides*. This
2 admission alone is fatal to Plaintiff's claim that AQ is completely destroyed.
3 Significantly, the expert admitted that peptides can be absorbed by the human body,
4 cross the BBB, and affect brain function. The expert's report does not even consider
5 the issue of peptides stemming from AQ digestion, much less the possibility that a
6 unique or uncommon peptide could result from the digestion of AQ and contribute to
7 memory support or healthy brain function. Moreover, the expert admitted that both
8 proteins and peptides can affect brain function without even crossing the BBB. The
9 expert proffers no opinion excluding that possibility with respect to AQ or its
10 derivative peptides after digestion. Taken together, these admissions completely
11 undermine Plaintiff's effort to prove his body chemistry allegations.

12 The core of Plaintiff's "game" may be illustrated via analogy. If amino acids are
13 like single letters and punctuation marks, a protein may be viewed as a long sentence
14 made of amino acids arranged in a particular sequence, and peptides may be viewed as
15 sentence fragments (e.g., words or clauses within the sentence). Plaintiff's allegation
16 that AQ, like any dietary protein, is broken down into common amino acids is akin to
17 saying that when the AQ "sentence" is broken down into individual letters and
18 punctuation marks, it cannot convey any meaning to a reader. Plaintiff's other
19 allegation that the amino acids resulting from the digestion of AQ are trivial and
20 indistinguishable from those generated from other proteins is like saying that all
21 sentences in the same language use the same alphabetical letters and punctuation marks.

22 The problem with Plaintiff's allegations are that his expert admits, and
23 Defendant's rebuttal experts confirm, that AQ is broken down into both amino acids
24 *and peptides*. Thus, the breakdown of the "AQ sentence" results in words or clauses in
25 addition to individual letters and/or punctuation. One or more of the fragments from the
26 AQ sentence could very well convey important meaning. Even a two or three-letter
27
28

1 fragment could have meaning; for example, “No” or “Out”.¹ A sentence fragment
 2 generated by breaking down the “AQ sentence” may also be very different from the
 3 fragments generated from the breakdown of other sentences. A peptide, like a sentence
 4 fragment such as a word or clause, may be unique among a large pool of different
 5 peptides. Even short fragments may be unusual or even unique. For example, the
 6 sentence fragment “sal” only appears once in this entire brief (other than in this
 7 sentence). This analogy helps demonstrate that Plaintiff’s expert’s admission that
 8 peptides result from the digestion of AQ is undoubtedly fatal to Plaintiff’s allegation
 9 that AQ is broken down into common amino acids that cannot have an effect on
 10 brain function.

11 Despite the admissions of Plaintiff’s expert, Plaintiff attempts to salvage his case
 12 by arguing that certain statements by Defendant’s lawyers to the Food and Drug
 13 Administration (FDA) are admissions by Quincy that AQ is completely digested into
 14 single amino acids. But Plaintiff takes those statements out of context as they are based
 15 on studies that clearly do not show complete digestion of AQ. Moreover, Plaintiff’s
 16 own expert affirmatively opines that AQ is not completely destroyed, and the rebuttal
 17 experts retained by Defendants agree. The rebuttal experts also agree with Plaintiff’s
 18 expert that the digestion of AQ may produce a non-trivial amount of peptides that could
 19 affect brain function, and Plaintiff’s expert clearly has not done any work to rule out
 20 that possibility.

21 For the foregoing reasons as detailed more fully below, Plaintiff’s sleight of hand
 22 is exposed. Plaintiff has not met, and cannot meet, his burden of proving that the AQ in
 23 Prevagen® is completely destroyed via digestion or that AQ provides only a trivial
 24 amount of amino acids that cannot affect brain function. Thus, Plaintiff cannot prevail
 25
 26

27 ¹ As noted in Part II.C, *infra*, it is a consensus among experts that peptides can carry out
 28 non-nutritional functions. Dr. Goodman testified that even dipeptides (i.e. “two-letter
 fragments,” to continue the analogy) could have a non-nutritional function. (Simon
 Decl. Ex. F (Goodman Dep. Tr.) at 64:10-14.)

on his motion, and instead, Defendant is entitled to summary judgment and Plaintiff's complaint should be dismissed.

II. FACTUAL BACKGROUND

A. Plaintiff Cannot Establish That AQ Is Destroyed By The Human Digestive System

1. Plaintiff's Expert Admits that AQ Is Not "Completely" or "Fully" digested

There is no evidence that AQ is completely digested into common amino acids. Plaintiff's expert could not have made this point any clearer:

Q. Do you have any evidence that AQ is entirely digested into single amino acids.

A. No.

(Simon Decl. Ex. A (Bazinet Dep. Tr.) at 121:6–8.)

Plaintiff's expert readily admits that AQ is not completely destroyed to common amino acids but is broken down into *both* amino acids *and* peptides. (Simon Decl. Ex. A (Bazinet Dep. Tr.), 110:17–22; 121:2–8; 122:5–16; 141:17–142:16; 256:13–23; 260:17–24.) It is also undisputed that peptides can be bioactive and affect brain function. (Simon Decl. Ex. A (Bazinet Dep. Tr.), 59:3–5; 142:11–16; 268:5–8; *see also* further discussion in Part II.D.4, *infra*.) Dr. Bazinet readily admits that peptides can be absorbed into the blood of humans and cross the BBB:

Q. Sometimes like you just recently testified, things aren't fully digested in the stomach by pepsin; right?

A. Correct.

Q. And so further breakdown occurs in the GI tract with those other enzymes; right?

A. Correct.

Q. And that breakdown is either into smaller peptides or single amino acids; right?

A. Correct.

1 Q. And a peptide can be broken down into smaller peptides?

2 A. Correct.

3 Q. It doesn't necessarily have to be broken down into single amino
4 acids in the GI tract; right?

5 A. Correct.

6 Q. And it can enter the blood as a peptide; right?

7 A. Correct.

8 Q. And we established earlier that peptides can cross the BBB;
9 right?

10 A. So –

11 Q. Certain peptides can cross the BBB; right?

12 A. Yes, we established that certain peptides can cross the BBB.

13 (Simon Decl. Ex. A (Bazinet Dep. Tr.), 141:17–142:16; *see also Id.* at 59:3–5; 142:11–
14 16; 268:5–8.)

15 **2. Plaintiff's Complaint, Expert Report, and Motion Obfuscate**
16 **And Ignore The Issue Of Peptides Resulting From AQ**

17 Despite the undisputed facts regarding the breakdown of AQ into peptides that
18 can be bioactive, Plaintiff's Complaint, expert report, and instant motion clearly attempt
19 to mislead the Court by sweeping the issue of peptides under the rug.

20 • The Complaint does not mention peptides. As the Court recognized,
21 Plaintiff's Complaint alleges, "(1) [the Product] cannot work as represented because
22 apoequorin, the only purported active ingredient in [the Product], is completely
23 destroyed by the digestive system and transformed into common amino acids no
24 different than those derived from other common food products". (Compl. ¶ 3; Doc. No.
25 34 at 2.)

26 • Plaintiff's expert report does not mention peptides in the summary of
27 opinions; it only mentions amino acids. (Doc No. 56-1 at ¶ 8.) Nor does the expert
28 report even consider the creation of peptides resulting from AQ digestion and their

1 potential effect on the human body. (*E.g.*, Simon Decl. Ex. A (Bazinet Dep. Tr.),
2 299:11–22; 261:18–263:8; Simon Decl. Ex. H (Bisordi Dep. Tr.) at 159:5–8, 257:5–16.)

3 • Plaintiff’s instant motion repeatedly states that AQ “is completely digested
4 and transformed into common amino acids” and that “even then a dose only provides a
5 trivial amount of these common amino acids.” (Doc. No. 62 at pp. 1, 4, 13.) The
6 instant motion further suggests that any peptides resulting from AQ digestion in the
7 stomach are “converted to amino acids.” (*Id.* at 5:1–25.)

8 The reason Plaintiff’s Complaint, expert report, and motion ignore the issue of
9 peptides is clear: Plaintiff cannot meet his burden of proving that AQ is completely
10 digested into common amino acids or is of such a trivial amount that it cannot support
11 memory or brain function if peptides remain in the picture.

12 3. Rebuttal Experts Retained by Defendant Confirm that AQ Is 13 Not “Destroyed” by Digestion

14 Rebuttal experts retained by Defendant confirm precisely what Dr. Bazinet
15 attempts to obfuscate in his report and what he clarified in deposition: AQ is not
16 completely destroyed in the human body. In his rebuttal expert report,
17 Gastroenterologist Dr. William Bisordi points out the various half-truths and
18 contradictions by Plaintiff and his expert regarding the digestion of AQ:

19 As the Court noted, Plaintiff has alleged that (1) “Prevagen
20 *cannot* work because apoaquorin is *completely* destroyed by
21 the digestive system and transformed into *common amino*
22 *acids*”; and (2) “*any amino acids* derived from the digestion of
Prevagen would be massively diluted and could have no
measurable effect on the brain.”

23 Upon my review, it is my professional opinion that Dr. Bazinet
24 did not provide any evidence whatsoever to show that
25 apoaquorin is “completely” digested to “common amino
26 acids,” in a human body or otherwise. Dr. Bazinet actually
27 stated in his expert report that “before apoaquorin even enters
the intestine it has been reduced down to amino acids *and*
possibly some small peptides.”

28 As discussed further below, amino acids and “small peptides”
are two different things. Therefore, Dr. Bazinet’s statement that

1 apoequorin is reduced to small peptides contradicts Plaintiff's
 2 first allegation that "Prevagen *cannot* work because
 3 apoequorin is *completely* destroyed by the digestive system
 and transformed into *common amino acids*."

4 (Simon Decl. Ex. D (Bisordi Report) at ¶¶ 17–18.)

5 Dr. Richard Goodman, an expert on protein digestion and allergenicity, similarly
 6 reports that he agrees with Dr. Bazinet's expert testimony that there is no evidence that
 7 AQ "is entirely digested into single amino acids." (Simon Decl. Ex. B (Goodman
 8 Report) at ¶ 34 (citing Simon Decl. Ex. A (Bazinet Dep. Tr.) at 121).) Dr. Goodman
 9 further opines that "one would expect that ingested AQ or peptides generated from
 10 ingested [AQ], would exit the stomach and be subject to absorption in the intestine."
 11 (*Id.* at ¶ 44.) Dr. Goodman also points out that Dr. Bazinet "never presented any
 12 evidence that, in humans, ingested [AQ] would be completely digested in the intestine
 13 upon exiting the stomach *before* absorption of the protein or the peptides derived from it
 14 can occur. (*Id.* at ¶ 45.) In addition, Dr. Michael Pezzone, an expert in protein
 15 digestion and absorption and bioactive peptides, attests in his rebuttal expert report that
 16 the absorption of small amounts of dietary proteins and large peptides from the
 17 gastrointestinal tract has been observed in healthy adult humans with no deleterious
 18 effects. (Simon Decl. Ex. C (Pezzone Report) at ¶¶ 15–24; *see also* Ex. G (Pezzone
 19 Dep. Tr.) at 76:8–24, 78:22–79:8, 80:24–81:11, 81:17–23, 111:20–112:18.)
 20 Dr. Pezzone further attests "one cannot rule out the possibility that [AQ] or a peptide
 21 derived from [AQ], can utilize one or more of the known mechanisms of absorption in
 22 the small intestine or elsewhere, across the gastrointestinal tract, in non-trivial amount."
 23 (Simon Decl. Ex. C (Pezzone Report) at ¶ 24; *see also* Ex. G (Pezzone Dep. Tr.) at
 24 175:10–21, 176:4–8, 177:12–17.) Dr. Pezzone further articulated in deposition that
 25 Dr. Bazinet merely speculates regarding the digestion of AQ. (*Id.* Ex. G (Pezzone Dep.
 26 Tr.) at 180:13–182:17.)

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B. Plaintiff Misconstrues Defendant’s Allergy Studies and Submissions to the FDA

Plaintiff incorrectly argues through his expert that Defendant’s own studies show that AQ is completely digested into common amino acids. (Doc. 62 at 6–7.) The “studies” cited by Plaintiff relate to and are derivative of a single study conducted in 2010 that evaluated the potential allergenicity of AQ (“the Allergenicity Study of 2010”). (Simon Decl. Ex. B (Goodman Report) at ¶ 14; Syverson Decl. Exs. C, D.) The principal author of the study reviewed Dr. Bazinet’s opinions on the Allergenicity Study of 2010 and determined Dr. Bazinet “showed a lack of understanding of what the study was designed to do and what it showed.” (Simon Decl. Ex. B (Goodman Report) at ¶ 16.)

As explained by Dr. Goodman, Plaintiff and his expert are wrong about the Allergenicity Study of 2010 for at least two reasons. **First**, the study did not test the digestion of AQ in the human body; it only tested the digestion of AQ by porcine pepsin, an enzyme found in the pig stomach, in a petri dish in a lab. (Simon Decl. Ex. B (Goodman Report) at ¶¶ 17–18; Ex. F (Goodman Dep. Tr.) at 35:3–9, 180:2–19; Ex. G (Pezzone Dep. Tr.) at 60:21–62:20.) The test for pepsin digestion *in vitro* can only help distinguish between proteins that do not have a clear history of causing dietary allergy (like AQ) from those that are found to be relatively stable in pepsin and have a greater probability of causing food allergic reactions. (Simon Decl., Ex. B (Goodman Report) at ¶¶ 20, 25, 31; Ex. F (Goodman Dep. Tr.) at 36:12–18, 54:7–21; Ex. G (Pezzone Dep. Tr.) at 60:21–62:20.) But the conditions for *in vitro* protein digestion by pepsin are optimized, and normal physiological conditions in the human stomach are not mimicked by the simple *in vitro* pepsin digestion model. (Simon Decl., Ex. B (Goodman Report) at ¶ 18, 31; Simon Decl. Ex. F (Goodman Dep. Tr.) at 35:3–9; Ex. G (Pezzone Dep. Tr.) at 38:9–39:4; Ex. H (Bisordi Dep. Tr.) at 58:11–59:4.) **Second**, the study was not designed to detect single amino acids or small peptides, just the full-length AQ protein or larger peptides. (Simon Decl., Ex. B (Goodman Report) at ¶¶ 32–44; Simon Decl.

Ex. F (Goodman Dep. Tr.) at 35:3–9, 182:1–6, 209:15–210:11, 213:16–23, 289:18–290:7.) Thus, the finding that after 30 seconds, 90% of the AQ was digested only means that 90% of the AQ was no longer full length with its amino acids still intact and linked together. In other words, an AQ protein with just some, but not all, amino acids missing through the operation of pepsin was counted among the 90% digested. (Simon Decl., Ex. B (Goodman Report) at ¶¶ 32–44; Ex. H (Bisordi Dep. Tr.) at 143:24–144:6, 151:14–25.) The study, therefore, does not indicate complete digestion.

Plaintiff argues that certain characterizations by Plaintiff’s attorneys of the Allergenicity Study of 2010 in a submission to the FDA constitute an admission that AQ is fully digested into individual amino acids. (Doc. No. 62 at 7:16–26.) Plaintiff’s argument should be rejected. **First**, the statement to the FDA was made in an entirely different context of determining whether AQ posed a risk of fish allergy. A discussion of the precise digestive breakdown of AQ was not required by the FDA. Critical to the disposition of the instant motion, none of the statements precludes a portion of peptides derived from AQ from being absorbed by the consumers before the non-absorbed portion of AQ is further digested in the intestine. **Second**, the statements are not supported by the studies upon which they rely as shown above and as attested by the author of the study himself and by the rebuttal experts retained by Defendant. (Simon Decl. Ex. F (Goodman Dep. Tr.) at 249:11–250:7, 260:19–261:23; Simon Decl. Ex. G (Pezzone Dep. Tr.) at 53:12–54:2, 54:18–55:2, 55:20–56:5, 56:10–20, 59:3–60:7; Ex. H (Bisordi Dep. Tr.) at 145:19–146:5, 152:8–153:6.) **Third**, again, Plaintiff’s argument is contradicted by his own expert, who admits that AQ is not completely digested into single amino acids. (Part II.A.1, *supra*.)

C. Plaintiff Has Not Established that the Amount of AQ Is Trivial

1. Plaintiff’s Expert Admits that AQ Provides More Than Just a Trivial Amount of Amino Acids

Plaintiff’s “dilution” argument compares the amount of *amino acids* generated by AQ with that generated by all dietary proteins. (Doc. No. 34 at 1). As stated above,

1 Dr. Bazinet conceded in deposition that AQ is not completely or fully destroyed via
 2 digestion because it is broken down into peptides, not just single amino acids. (Simon
 3 Decl. Ex. A (Bazinet Dep. Tr.), 110:17–22; 121:2–8; 122:5–16; 141:17–142:16;
 4 256:13–23; 260:17–24.) Dr. Bazinet testified that proteins may vary in terms of how
 5 much of the protein is broken down into single amino acids as opposed to peptides.
 6 (Simon Decl. Ex. A (Bazinet Dep. Tr.), 259:2–9; *see also* Simon Decl. Ex. H (Bisordi
 7 Dep. Tr.) at 156:24–157:3.) But because Dr. Bazinet did not test AQ, he has no
 8 knowledge of the peptides resulting from the digestion of AQ or how AQ may compare
 9 to other dietary proteins in this respect. (Simon Decl. Ex. A (Bazinet Dep. Tr.),
 10 297:11–298:15.) Although he opines regarding the digestion of AQ in the gut,
 11 Dr. Bazinet conceded in deposition that he performed no digestion studies on AQ and,
 12 in fact, is not even a specialist on protein digestion. (*Id.*, 35:14–36:10; 37:7–10;
 13 38:1 11.)

14 Dr. Bazinet testified that the mixture of AQ and other ingredients in the
 15 Prevacen® capsules could delay digestion of AQ in the gut, but he has not run any
 16 studies to determine whether the mixture would have any effect on digestion of AQ.
 17 (Simon Decl. Ex. A (Bazinet Dep. Tr.), 116:16–22; 126:16–21.) Nor is Dr. Bazinet
 18 aware of any studies regarding the possible effect of the Prevacen® mixture on the
 19 digestion of AQ. (*Id.*, 126:22–127:13.) Dr. Bazinet is aware of reports showing the
 20 existence of proteins that are resistant to pepsin, the digestive enzyme in the stomach,
 21 and he has not ruled out the possibility that AQ could be a pepsin resistant protein. (*Id.*,
 22 133:23–134:10.)

23 Dr. Bazinet testified that it was mathematically possible for a unique small
 24 peptide (small enough to cross the BBB) to be generated by a partial digestion of AQ.
 25 (*Id.*, 299:11–22; 261:18–263:8.) Dr. Bazinet’s report does not even consider this issue
 26 of peptides resulting from AQ digestion, much less the possibility that a unique or
 27 uncommon peptide small enough to cross the BBB could result from digestion of AQ.
 28 In fact, Dr. Bazinet only “eyeballed” AQ’s amino acid sequence and could not

1 remember any particular portion of it. (*Id.*, 243:8–17.) He testified that he has not
 2 determined whether the peptides generated from AQ completely overlap with those of
 3 other dietary proteins, including proteins from bread and hotdogs, although a test could
 4 be run to make such a determination. (*Id.*, 297:11–298:15.) Thus, Dr. Bazinet renders
 5 no opinion of the potential peptides that could result from AQ, whether they could cross
 6 the BBB, and how common or uncommon these potential AQ-derived peptides are
 7 compared to the peptides that could be generated by all other dietary proteins.

8 In fact, Dr. Bazinet testified that dietary proteins may contain 50 different types
 9 of amino acids, and the potential combinations of amino acid sequences or peptides
 10 resulting from digestion of dietary proteins could be infinite. (Simon Decl. Ex. A
 11 (Bazinet Dep. Tr.), 287:15–288:2 (“There’s all kinds of combinations. It goes on
 12 forever.”).) Although he was unable to calculate the figure, Dr. Bazinet testified that
 13 the number of different types of possible tripeptides (a sequence of three amino acids)
 14 or quadropeptides/tetrapeptides (a sequence of four amino acids) that could result from
 15 the partial breakdown of all dietary proteins would be very large. (*Id.* 287:15–289:15.)
 16 The larger the number of *possible* peptides, the less likely that the peptides *actually*
 17 *generated* by the limited number of dietary proteins a human ingests could cover all
 18 possibilities, including covering *all* possible peptides that AQ could generate.
 19 Dr. Bazinet did not provide any evidence on the likelihood of the proteins in a human
 20 diet actually generating *all* tripeptides and quadropeptides that AQ could generate. (*Id.*,
 21 297:11–298:15.)

22 In addition, in forming his opinions, Dr. Bazinet did not consider the
 23 recommended timing of Prevacen® supplementation. The prescribed use is to take
 24 Prevacen® in the morning with or without food, but not simultaneously with the
 25 purported 75,000 mg of other proteins in the average daily diet. (Simon Decl. Ex. A
 26 (Bazinet Dep. Tr.), 286:5–20; 287:6–14.)

2. Rebuttal Experts Retained by Defendant Confirm that AQ May Generate Nontrivial Peptides

Rebuttal experts retained by Defendant and who have testified in this case agree with Dr. Bazinet that peptides carry out non-nutritional functions. They further confirm that Plaintiff has presented no evidence showing that ingested AQ results in such a trivial amount that it cannot biologically affect memory or support brain function. (Simon Decl. Ex. B (Goodman Report) at ¶¶ 46–50; Ex. C (Pezzone Report) at ¶¶ 22–24; Ex. D (Bisordi Report) at ¶ 15; Ex. H (Bisordi Dep. Tr.) at 130:3–13, 135:6–16.) Dr. Richard Goodman testified that peptides as small as dipeptides (made up of two amino acid residues strung together) could have non-nutritional function. (Simon Decl. Ex. F (Goodman Dep. Tr.) at 64:10–14, 128:6–11 (discussing “signaling peptides”), 193:14–16, 231:19–25 (discussing “bioactive peptides”).) Dr. Goodman further testified that Dr. Bazinet’s “dilution” argument was irrelevant because he does “not believe that individual amino acids make up the effect of apoaeguorin,” rather the whole protein or peptides would have the effect. (*Id.* at 63:12–64:14; *see also* Simon Decl. Ex. B (Goodman Report) at ¶¶ 46–50.) In addition, Dr. Michael Pezzone testified about therapeutic peptides and also peptides potentially having bioactive functions in small amounts. (Simon Decl. Ex. G (Pezzone Dep. Tr.) at 7:8–24, 22:18–22, 79:4–8, 94:23–95:1.) Dr. Pezzone also pointed out that peptides “are all different” in terms of their structures, capabilities and characteristics. (*Id.* at 59:21–60:7.) Furthermore, Gastroenterologist Dr. William Bisordi testified that a small amount of peptides generated from the digestion of ingested proteins can have biological or therapeutic effects. (Simon Decl. Ex. H (Bisordi Dep. Tr.) at 62:19–23, 63:18–65:23, 68:16–20, 76:10–16, 80:9–16, 90:1–16, 112:1–19, 113:10–114:17, 115:20–116:11, 222:13–223:10, 225:15–227:5, 264:12–21, 265:19–266:24.)

D. Plaintiff Has Not Established That AQ Cannot Pass The Blood-Brain Barrier

1. Plaintiff's Expert Admits, and Defendant's Experts Further Confirm, that Peptides Resulting from the Digestion of Prevacen® Can Cross the BBB and Affect Neuron Function

Although Dr. Bazinet testified he is not aware of any dietary proteins crossing the BBB, he readily conceded in deposition that peptides can cross the BBB and affect brain function. (Simon Decl. Ex. A (Bazinet Dep. Tr.), 59:3–5; 142:11–16; 268:5–8; *see also* 261:18–263:8 (further establishing that peptides can be small enough and also have high lipid solubility to cross the BBB).) Dr. Bazinet also testified that there may be receptors that allow peptides derived from AQ to cross the BBB. (*Id.*, 238:15–239:17.) What is more, Dr. Bazinet testified that he has not ruled out the possibility that AQ could bind to a serum protein that could then bind to a BBB receptor to transport AQ across the BBB. (*Id.*, 245:14–246:11.)

Importantly, Dr. Bazinet testified that a single protein or peptide molecule can affect brain function. (Simon Decl. Ex. A (Bazinet Dep. Tr.), 277:10–278:10; 278:25–279:13.) Specifically, he testified that proteins and peptides can serve as “ligands,” ligands can bind to receptors in neurons, and a single molecule of a ligand may be sufficient to activate a single neuron and affect brain function. (*Id.*) Dr. Bazinet does not rule out the possibility of AQ or a peptide resulting from AQ acting in such a manner.

Defendant retained an expert to rebut the opinions of Dr. Bazinet regarding the BBB. Consistent with Dr. Bazinet's admissions in deposition, Dr. Spencer's rebuttal report shows that Dr. Bazinet failed to conduct the necessary research, testing, and work to rule out the possibility of AQ passing through the BBB. Based upon his background in neuroscience and delivery of proteins and peptides across the blood-brain barrier, Dr. Spencer raises four possibilities for AQ to pass through the BBB that Dr. Bazinet did not rule out in his report or deposition. (Simon Decl. Ex. E (Spencer Report) ¶¶ 15,

20, 23, 25, and 27.) These include: (1) receptor mediated transcytosis, (*Id.* ¶¶16–20), (2) cell penetrating peptide, (*Id.* ¶¶ 21–23), (3) “sink” hypothesis, (*Id.* ¶¶ 24–25), and (4) “leaky” BBB, (*Id.* ¶¶ 26–27). In particular, Dr. Spencer’s report establishes that “Dr. Bazinet fails to rule out BBB transcytosis, nor could he rule it out without completing extensive *in vitro* and *in vivo* analysis of AQ in a controlled environment of the BBB.” (*Id.* ¶ 20.) Dr. Spencer’s report further shows that Dr. Bazinet “does not provide sufficient information and has not conducted the appropriate studies to determine whether AQ does or does not contain such a [cell penetrating] peptide to allow AQ to cross the BBB.” (*Id.* ¶ 23.) Moreover, Dr. Spencer’s report concludes that Dr. Bazinet has not conducted sufficient testing to rule out the possibility that AQ can affect brain function without even having to cross the BBB under a “sink” hypothesis. (*Id.* ¶ 25.) Lastly, Dr. Spencer highlights that leaky BBB’s in elderly adults are not as rare as Dr. Bazinet opines and perhaps relatively common with the elderly consumers among whom Prevagen® is marketed and tested. (*Id.* ¶¶ 26–27.)

Notably, Dr. Spencer further testified in deposition that his opinions would apply equally to peptides and that Dr. Bazinet failed to rule out the possibility of a peptide generated from AQ passing through the BBB. (Simon Decl. Ex. I (Spencer Dep. Tr.) at 242:22–243:20.)

2. Plaintiff’s Expert Admits, and Defendant’s Rebuttal Experts Further Confirm, that Proteins and Peptides Do Not Even Need to Cross the BBB to Affect Brain Function

Dr. Bazinet testified that proteins and peptides can affect memory without ever crossing the BBB. (Simon Decl. Ex. A (Bazinet Dep. Tr.), 75:4–76:7.) Dr. Bazinet’s report does not discuss, let alone rule out, the possibility that AQ could have an indirect—but real—effect on memory. More specifically, Dr. Bazinet testified that peptides can have functional properties, rather than just nutritional properties, and peptides can affect brain function without crossing the BBB in view of their functional properties. (*Id.*, 271:18–272:6; 272:19–273:24; 279:20–280:2.) Moreover, Dr. Bazinet

1 testified that both proteins and peptides can act as signaling molecules, thereby
 2 affecting brain function whether or not they actually enter the brain. (*Id.*, 274:2–18.)
 3 This possibility is further supported by Sr. Spencer’s “sink” hypothesis. (Simon Decl.
 4 Ex. E (Spencer Report) ¶¶ 24–25.)

5 **III. LEGAL STANDARD**

6 The standard for evaluating motions for summary judgment is well settled and
 7 also set forth in Defendant’s competing motion for summary judgment. (Doc. No. 55.)
 8 Under Federal Rule of Civil Procedure 56(a), summary judgment is permitted only “if
 9 the movant shows that there is no genuine dispute as to any material fact and the
 10 movant is entitled to judgment as a matter of law.” Material facts are those that might
 11 affect the outcome of the case. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254
 12 (1986). A dispute as to a material fact is “genuine” if the evidence is such that “a
 13 reasonable jury could return a verdict for the nonmoving party.” *Id.* The question is
 14 “whether a jury could reasonably find either that the [moving party] proved his case by
 15 the quality and quantity of evidence required by the governing law or that he did not.”
 16 *Id.* at 254 (*emphasis omitted*). “[A]ll justifiable inferences are to be drawn in [the
 17 nonmovant’s] favor.” *United Steelworkers of Am. v. Phelps Dodge Corp.*, 865 F.2d
 18 1539, 1542 (9th Cir. 1989) (en banc) (quoting *Liberty Lobby*, 477 U.S. at 255).

19 The moving party bears the burden of informing the Court of the basis for its
 20 motion and identifying those portions of the pleadings, depositions, evidence, and
 21 affidavits that it contends demonstrate the absence of a genuine issue of material fact.
 22 *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). A party opposing a summary
 23 judgment motion may “cit[e] to particular parts of materials in the record” showing that
 24 there is a genuine issue for trial. Fed.R.Civ.P. 56(c)(1)(A); *see also Liberty Lobby*, 477
 25 U.S. at 250. The opposing party need not show the issue will be resolved conclusively
 26 in its favor. *See Liberty Lobby*, 477 U.S. at 248–49. All that is necessary is submission
 27 of sufficient evidence to create a material factual dispute, thereby requiring a jury or
 28 judge to resolve the parties’ differing versions at trial. *See Id.*

IV. ARGUMENT

A. Plaintiff Has No Affirmative Evidence That AQ Is Completely Destroyed Or That It Is Of Such Trivial Amount That It Cannot Affect Brain Function.

Under California law, Plaintiff “bears the burden of proving the advertising claims to be false or misleading.” *See Nat’l Council Against Health Fraud, Inc. v. King Bio Pharm., Inc.*, 107 Cal. App. 4th 1336, 1347-48 (2003) (“*King Bio*”) (plaintiffs have the burden of producing evidence of the falsity of the advertising claims through “testing, scientific literature, or anecdotal evidence”); *Johns v. Bayer Corp.*, No. 09CV1935 AJB DHB, 2013 WL 1498965, at *30, 36, 40, 43 (S.D. Cal. Apr. 10, 2013), *appeal dismissed* (Sept. 19, 2013), (“[I]n a false advertising case under the UCL and CLRA, the plaintiff ‘bears the burden of proving that the defendant’s advertising claim is false or misleading’.”) (quoting *King Bio*); *Stanley v. Bayer Healthcare LLC*, No. 11cv862–IEG (BLM), 2012 WL 1132920, at *6 (S.D. Cal. Apr. 3, 2012) (granting summary judgment motion where plaintiff’s claims relied on inconclusive expert testimony and defendant had not substantiated its labeling); *Chavez v. Nestle USA, Inc.*, No. CV 09-9192, 2011 WL 2150128, at *5-6 (C.D. Cal. May 19, 2011); *Fraker v. Bayer Corp.*, No. CV F 08-1564-AWI GSA, 2009 WL 5865687, at *8 (E.D. Cal. Oct. 6, 2009). Plaintiff cannot meet his burden by claiming that the representations are unsubstantiated. *Id.*; *Johns v. Bayer Corp.*, No. 09CV1935 AJB DHB, 2013 WL 1498965, at *30, 36, 40, 43 (S.D. Cal. Apr. 10, 2013), *appeal dismissed* (Sept. 19, 2013); *Fraker v. Bayer Corp.*, No. CV F 08-1564-AWI GSA, 2009 WL 5865687, at *8 (E.D. Cal. Oct. 6, 2009).

Plaintiff rightly recognizes that he bears the burden of proving the only currently pending issues identified by the Court: Plaintiff’s body chemistry allegations. To survive summary judgment, Plaintiff must support his body chemistry allegations with **affirmative evidence** regarding Prevagen® or AQ, specifically. *See King Bio*, 107 Cal. App. 4th at 1347; *Johns v. Bayer Corp.*, 2013 WL 1498965, at *36 (“Accordingly, **in**

1 **the absence of affirmative scientific evidence** available during the Class Period that
 2 proves that zinc and vitamin E did not support prostate health . . . Plaintiffs' claims are
 3 based on "lack of substantiation" rather than proof of falsity.") (*Emphasis added*).

4 Plaintiff's sole expert does not offer any affirmative evidence that Prevagen® or
 5 AQ, specifically, is completely destroyed via digestion or is of such trivial amount that
 6 it cannot affect brain function. Part II.A, *supra*; Part II.C, *supra*; see *King Bio*, 107 Cal.
 7 App. 4th at 1347; *Johns v. Bayer Corp.*, 2013 WL 1498965, at *1, 36, 40, 43; *cf*
 8 *Brookhaven Typesetting Svcs., Inc. v. Adobe Sys., Inc.*, 332 Fed. Appx. 387, 390 (9th
 9 Cir. 2009) (affirming summary judgment because "the expert's declaration did not
 10 provide a sustainable basis upon which a triable case of misappropriation could be
 11 founded" and "[t]he only specific examples were conclusory, with no detail provided").

12 The affirmative evidence a plaintiff has the burden to produce at the summary
 13 judgment stage must be **specific**. It must be directly related to the accused product. In
 14 *King Bio*, the plaintiff alleged that defendant falsely advertised the efficacy of its
 15 homeopathic drug products. 107 Cal. App. 4th at 1347. Plaintiff presented expert
 16 testimony of the inefficacy of homeopathic remedies in general, but presented no
 17 evidence concerning the efficacy of *King Bio*'s products specifically. *Id.* The court
 18 noted that "homeopathic remedies are marketed and readily available for testing by a
 19 plaintiff," and that just because the plaintiff did "not wish to bear the expense of
 20 proving its case does not mean that the burden and expense should be shifted to *King*
 21 *Bio*." *Id.* at 1348.

22 Accordingly, the California Court of Appeals affirmed the Superior Court's
 23 granting of judgment for *King Bio*, holding that the plaintiff had failed to meet its
 24 burden "of producing evidence that the challenged advertising claims of *King Bio* are
 25 false or misleading." *Id.* at 1344; see also *Id.* at 1340; *Stevens v. JPMorgan Chase*
 26 *Bank, NA.*, No. C09-03116 SI, 2010 WL 329963, at *4-5 (N.D. Cal. Jan. 20, 2010)
 27 (dismissing false advertising and misleading practices complaint based on *King Bio*
 28 when complaint provided nothing more than mere labels and conclusions).

1 Much like the plaintiff's expert in *King Bio*, what Dr. Bazinet offers here is a
 2 theory regarding dietary proteins in general, and not the product at issue. In support of
 3 his opinion that the Prevagen® advertising claims are false, Dr. Bazinet, Plaintiff's sole
 4 expert, opines on three points: (1) Dietary proteins are "completely" or "fully" digested
 5 to single amino acids; (2) AQ would generate the same amino acids as the other dietary
 6 proteins, so the effect of 10 mg of AQ would be "diluted" by 75,000 mg of other
 7 proteins a person ingests every day; and (3) Ingested proteins cannot have any effect on
 8 brain function or memory. None of these opinions is based on any evidence specific to
 9 AQ or Prevagen®. Therefore, Plaintiff has failed to present any competent evidence to
 10 support his summary judgment motion. Indeed, given the lack of affirmative evidence
 11 supporting his body chemistry allegations, Plaintiff cannot prevent summary judgment
 12 in favor of Quincy as set forth in Defendant's competing motion for
 13 summary judgment.

14 **B. The Generalized Opinions Plaintiff's Expert Offered Have Been**
 15 **Proven Wrong By *His Own Testimony* And Further Discredited By**
 16 **The Rebuttal Experts**

17 As shown in the fact section above, each of the generalized opinions by
 18 Dr. Bazinet is contradicted by his report, his deposition testimony, and the opinions of
 19 rebuttal experts retained by Defendant.

20 With respect to Dr. Bazinet's first point, that of "complete" and "full" digestion
 21 of AQ, he readily conceded during deposition that (a) he had never studied or tested
 22 Prevagen® or AQ; (b) AQ is digested into both amino acids *and* peptides; (c) some
 23 peptides can affect brain function without crossing the BBB; and (d) some peptides can
 24 cross the BBB and affect brain function. (Part II.A.1, *supra*.) As shown above,
 25 Dr. Bazinet's report does not even consider, let alone address, the issue of peptides
 26 resulting from AQ digestion or the possibility that a unique or uncommon peptide small
 27 enough to cross the BBB could result from digestion of AQ. In fact, Dr. Bazinet
 28 renders no opinion whatsoever regarding the potential peptides that could result from

1 AQ digestion and whether they could cross the BBB. Defendant's rebuttal experts
 2 further confirm that AQ is not completely hydrolyzed into common amino acids. (Part
 3 II.A.3, *supra*.)

4 On Dr. Bazinet's second point, that of "dilution" by dietary proteins, the rebuttal
 5 experts retained by defendant refute Dr. Bazinet's opinion and show how it is based on
 6 the false assumption that all dietary proteins, including AQ, are digested all the way
 7 down to amino acids. (Part II.C.2.) Bioactive peptides in very small amounts can have
 8 biological effects. (*Id.*) What is more, Dr. Bazinet's deposition testimony undercuts his
 9 "dilution" opinion and supports the opinions of Defendant's rebuttal experts.
 10 Dr. Bazinet's report does not consider the recommended timing of AQ ingestion (to be
 11 taken first thing in the morning on an empty stomach) and how that may affect the
 12 body's digestion and absorption of AQ. (Simon Decl. Ex. A (Bazinet Depo.), 286:5–
 13 20; 287:6–14.) Plaintiff argued that "common amino acids" generated by protein
 14 digestion are "no different" from each other regardless of their sources. (Doc. No. 34 at
 15 1). But Dr. Bazinet testified that it was mathematically possible for AQ to generate a
 16 *unique* small peptide (small enough to cross the BBB) that is different from all peptides
 17 generated by other dietary proteins. (Simon Decl. Ex. B (Bazinet Depo.), 299:11–22;
 18 261:18–263:8.) If an AQ-derived peptide is uncommon or even unique, it would not be
 19 "diluted" to trivial amounts by other types of peptides generated by other dietary
 20 proteins. Furthermore, even if "dilution" of AQ-derived peptides would occur,
 21 Dr. Bazinet acknowledged that a single molecule of peptide can affect brain function.
 22 (*Id.*, 277:10–278:10; 278:25–279:13.) For example, Dr. Bazinet testified that proteins
 23 and peptides can be ligands, ligands can bind to receptors in neurons, and a single
 24 molecule of a ligand may be sufficient to activate a neuron and affect brain function.
 25 (*Id.*) Dr. Bazinet does not discuss, let alone rule out the possibility of AQ or an AQ-
 26 derived peptide acting in such a manner. In that sense, no amount of a protein or
 27 peptide that acts as a ligand is trivial. A single molecule could be effective.
 28

On Dr. Bazinet's third point, that ingested proteins cannot affect brain function, his deposition testimony revealed three important points that contradicted his earlier, bare assertion. **First**, he testified that proteins and peptides can affect memory indirectly *without* crossing the BBB. (Simon Decl. Ex. B (Bazinet Depo.), 75:4–76:7; 271:18–272:6; 272:19–273:24; 279:20–280:2; 274:2–18.) His report does not discuss, much less exclude, the possibility that AQ has an indirect effect on brain function or memory. **Second**, Dr. Bazinet, again, testified that peptides generated by partial digestion of ingested proteins *can* cross the BBB. (*Id.*, 59:3–5; 142:11–16; 268:5–8.) Dr. Bazinet also testified that there may be receptors that allow peptides derived from AQ to cross the BBB. (*Id.*, 238:15–239:17.) **Third**, Dr. Bazinet testified that a single molecule that crossed the BBB and entered the brain could act as a ligand and activate a neuron. (*Id.*, 277:10–278:10; 278:25–279:13.) Consistent with these admissions, Defendant's rebuttal expert further confirms that Dr. Bazinet has not conducted the necessary research, testing, and work to rule out the possibility that AQ, or a bioactive peptide resulting from the digestion of AQ, could pass through the BBB or have a biological effect on memory or support brain function without crossing the BBB. (Part II.D, *supra*.)

Therefore, Plaintiff's reliance on a generalized, unsupported, rescinded, and rejected "complete" digestion and "dilution" theory is insufficient to support Plaintiff's motion for summary judgment. In fact, summary judgment should be granted in favor of Defendant. Plaintiff should not be permitted to have his case move forward on bare hypotheses and theories. *King Bio* 107 Cal. App. 4th at 1345–46.

V. CONCLUSION

For the foregoing reasons, in light of the absence of affirmative evidence submitted by Plaintiff and his expert, Plaintiff has not met, and cannot meet, his burden of proffering evidence of his body chemistry allegations, much less evidence to support his motion for summary judgment. Given his expert's testimony and that of Defendant's rebuttal experts, there is no genuine issue of material fact that AQ is not

1 completely destroyed via digestion. Nor is there a genuine issue of material fact that
2 Plaintiff has not put forth evidence to support his claim that AQ only produces a trivial
3 amount of amino acids that cannot biologically affect memory or support brain
4 function. Thus, pursuant to this Court's Order, Plaintiff cannot proceed with his false
5 advertising lawsuit. At a minimum, Defendant's rebuttal experts create disputed issues
6 as to Plaintiff's body chemistry allegations, and Plaintiff's motion must be denied.
7 Therefore, Quincy respectfully requests that this Court deny Plaintiff's motion for
8 partial summary judgment and, instead, enter judgment in favor of Quincy and against
9 Plaintiff in this case.

10 Dated: December 23, 2015

CALL & JENSEN
A Professional Corporation

11
12
13 By: /s/ Joshua G. Simon
Joshua G. Simon

14 Attorneys for Defendant
15 Quincy Bioscience, LLC
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CERTIFICATE OF SERVICE

I hereby certify that on December 23, 2015, I electronically filed the foregoing document described as **DEFENDANT'S OPPOSITION TO PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT** with the Clerk of the Court using the CM/ECF System which will send notification of such filing via electronic mail to all counsel of record.

/s/ Joshua G. Simon
Joshua G. Simon